

**510(k) SUMMARY**

Trade Name: Steerable Guide Catheter

Common Name: Steerable Catheter

Classification Name: Class II, Catheter Introducer, 21 CFR 870.1280

Device Code: DRA

Manufacturer's Name: Evalve, Inc. JAN 13 2010

Manufacturer's Address: 4045 Campbell Avenue  
Menlo Park, CA 94025

Corresponding Official: Sevrina Ciucci

Title: Regulatory Affairs Consultant

Address: 4045 Campbell Avenue  
Menlo Park, CA 94025

Phone: (408) 316-4837

Date of Preparation: December 16, 2009

Predicate: K083793 and K091596 Evalve Steerable Guide Catheter

Intended Use: The Evalve Steerable Guide Catheter is used for introducing various cardiovascular catheters into the left side of the heart through the interatrial septum.

Device Description: The Steerable Guide Catheter consists of a Steerable Guide (Guide) and a Dilator provided EO sterile and for single-use only. The Steerable Guide Catheter consists of a distal and proximal catheter shaft, a radiopaque tip ring, a handle with a steering knob, a hemostasis valve with a luer lock flush port, a Dilator with a single central lumen and an atraumatic distal tip. The central lumen of the Guide allows for aspiration of air and infusion of fluids such as saline, and serves as a conduit during introduction and or exchange of the Dilator and ancillary devices (e.g. catheters) that have a maximum diameter of .204". The atraumatic distal tip of the Steerable Guide Catheter is radiopaque to allow visualization under

fluoroscopy. The Dilator consists of a radiopaque shaft, an echogenic feature at the distal tip, a hemostasis valve with a flush port and an internal lumen designed to accept ancillary devices that have a maximum diameter of 0.035" (e.g. needles or guidewires). The Steerable Guide Catheter and Dilator are packaged in two sealed Tyvek pouches, and boxed in a shelf-cardboard carton.

**Comparison to Predicate:**

The subject device is substantially equivalent to the predicate devices with respect to intended use, indications for use, labeling, patient contacting materials, technological and performance characteristics, ergonomics of patient-user interface, overall dimensions, packaging, and sterilization.

**Substantial Equivalence:**

Bench testing demonstrated that the subject device met performance specifications and is substantially equivalent to the predicate devices.

**Conclusions:**

The Evalve Steerable Guide Catheter and Dilator has the same indications for use and technological characteristics and performs as well or better than the predicate devices.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

Evalve Inc.  
c/o Ms. Sevrina Ciucci  
Evalve Regulatory Consultant  
4045 Campbell Ave.  
Menlo Park, CA 94025

JAN 13 2010

Re: K093866  
Trade/Device Name: Evalve Steerable Guide Catheter  
Common Name: Catheter, Steerable  
Regulation Number: 21 CFR 870.1280  
Regulatory Class: II  
Product Code: DRA  
Dated: December 16, 2009  
Received: December 17, 2009

Dear Ms. Ciucci:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use Statement

510(k) Number (if known): K093866

Device Name: Steerable Guide Catheter

Indication for Use:

The Evalve Steerable Guide Catheter is used for introducing various cardiovascular catheters into the left side of the heart through the interatrial septum.

Prescription Use X  
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-- CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Dennis R. Volney  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K093866